K113728

510(k) SUMMARY

Submitter Name:	HansBiomed Corp.
Submitter Address:	8 Floor SK Building Seongsu 1-ga Seongdong-gu Seoul, 133-110 Korea
Contact Person:	Ms. Lucy Choi
Phone Number:	0082 2 466 2266
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Date Prepared:	December 19, 2011
Device Trade Name:	SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty
Device Common Name:	Resorbable bone void filler, human bone graft material
Classification Number:	21 CFR 888.3045
Product Code and Classification Name	MQV and MBP Filler, bone void, calcium compound Filler, bone void, Osteoinduction (w/o Human Growth Factor)
Device Class	II
Predicate Devices:	K040419, DynaGraft II Gel and Putty, IsoTis OrthoBiologics, Inc. K053319, Allomatrix® Cusotm Putty, Wright Medical Technology, Inc.
Statement of Intended Use:	The SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, and ExFuse™ Putty products are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are intended to be gently packed into bony voids or gaps of the skeletal system (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
Device Description:	The SurFuse™ and ExFuse™ family of products are derived from human allograft bone tissue that is processed into a powder and demineralized using a hydrochloric acid process. The demineralized bone matrix (DBM) is combined with a resorbable carrier, carboxymethylcellulose (CMC) and formulated into a putty or gel-like consistency. The ExFuse™ products also contain cancellous bone powder. The products are provided sterile for single patient use.

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Safety:	The donor bone is obtained from AATB-certified tissue banks in the United States. The tissues are screened for the standard panel of infectious viruses. Further the manufacturing and sterilization processes have been validated to inactivate the HIV-1, Bovine Herpes Virus (BHV), Bovine Viral Diarrhea Virus (BVDV), Hepatitis A Virus (HAV) and Porcine Parvovirus (PPV). Biocompatibility testing, according to ISO 10993, has been performed and the devices have been shown to be safe, non-toxic and biocompatible.
Performance:	The devices were tested successfully to fully characterize their osteoconductive ability to grow bone in the *in vivo* rabbit spinal model. They also have been tested *in vivo* in the athymic (nude) rat muscle pouch model and were shown to have osteoinductive potential, in that new bone grew within the muscle tissue. The osteoinductive potential also was evaluated with a surrogate, *in vitro* BMP-2 ELISA, assay. Results from that assay were correlated with results from the same lots in which bone successfully formed in the athymic rat. Each lot of the SurFuse™ and ExFuse™ devices will be evaluated for osteoinductive potential using the *in vitro* assay. Osteoinduction assay results observed in surrogate assessments should not be interpreted to predict clinical performance in human subjects.
Comparison to the Predicate Devices:	These device families, with respect to material composition, device characteristics and intended use, are substantially equivalent to the two predicate device families.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Hans Biomed Corporation
% Trisler Consulting
Ms. Patsy J. Trisler, JD, RAC
Regulatory Consultant
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

Letter Dated: November 15, 2012

Re: K113728
Trade/Device Name: SurFuse™ Gel and Putty, ExFuse™ Gel and Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV, MBP
Dated: October 22, 2012
Received: October 25, 2012

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K113728

Device Name: SurFuse™ Gel and Putty
ExFuse™ Gel and Putty

Indications for Use:

The SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, and ExFuse™ Putty products are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are intended to be gently packed into bony voids or gaps of the skeletal system (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Prescription Use __X_
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K113728